

ADVANCED DERMATOLOGY AND COSMETIC CARE

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January 29, 2001

FDA
c/o Dockets Management Branch (HFA-305)
5630 Fishers Lane
Suite 1061
Rockwell, MD 20857

RE: Sunscreen regulations

To Whom It Concerns,

I believe the anticipated sunscreen monographs scheduled for release later this year needs drastic changes.

As a dermatologist, I have seen that many years have been required to educate the population. One of the foremost aspects of education is clarifying that a minimum SPF 15 is needed, especially in sunny climates such as Southern California. To lump an SPF 11 sunscreen with an SPF 29, is an egregious error. It will make people think they are having adequate protection when in fact they have virtually no protection. What kind of bureaucratic thinking was going on to combine an SPF 11 with an SPF 29 in one category? Surely there was not a dermatologist involved in this decision. I doubt that even the sunscreen manufacturers would be happy with that situation.

The end result will be that all sunscreens labeled moderate (from 11 to 29) will basically be an 11, since no sunscreen company is going to pay the extra money to manufacture an SPF 29 when it is going to be lumped with the SPF 11's. Do you understand this-point? If not, I suggest you take one of your bureaucrats, send them to Arizona, California; or Hawaii, and have them use an SPF 11 on one side, of their face and an SPF 29 on the other over a three day sunny summer period and see what happens.

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RE: Sunscreens
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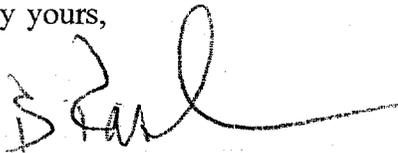
January 29, 2001

I also firmly believe that sunscreens greater than 30 have an important place in the spectrum of treatment. The main problem is most people do not put on enough sunscreen. Therefore, having them use a #45 and not put on enough sunscreen, gives them a real life reading of somewhere above 15 to 30, which is necessary. Additionally, in strong sunny environments such as the beach in Southern California in summer, people are well known to bum through a 30 and do well with a 45.

As an additional issue, I strongly recommend that the FDA re-evaluate your water resistance categorizations. Significant technological improvement in sunscreens, including the use of silicone and microsphere technology, means that these sunscreens do in fact last for a number of hours, even in a water saturated environment. As a surfer, I can attest to the duration of six and eight hour waterproof sunscreens. Physically it is impossible to send a child off to school with instructions to reapply sunscreen every two hours or expect them to remember to reapply the sunscreen prior to after school sports. The all day eight hour sunscreens, in fact, do last the eight hours based on scientific studies. These sunscreens afford the parent a degree of comfort and their children significant protection in this group who would never re-apply sunscreens every two hours.

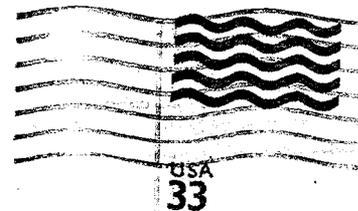
I believe that significant technological improvements in sunscreens makes the anticipated FDA monograph obsolete. I strongly hope that you reconsider your regulations.

Sincerely yours,

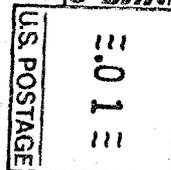
A handwritten signature in black ink, appearing to read "B. Raskin", with a long horizontal flourish extending to the right.

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